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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/746,670	12/22/2000	Shanta M. Modak	A33432 070050.1354	1401

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NEW YORK, NY 10112

EXAMINER

BENNETT, RACHEL M

ART UNIT	PAPER NUMBER
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1615

DATE MAILED: 09/24/2003

10

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/746,670

Applicant(s)

MODAK ET AL.

Examiner

Rachel M. Bennett

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 09 July 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-13 and 17-22 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-13, 17-22 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 9.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

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### DETAILED ACTION

The examiner acknowledges receipt of Amendment A and IDS filed 7/9/03.

#### *Double Patenting*

1. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

2. Claims 1-2, 8-9, 17, 21-22 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-4 of copending Application No. 09/746658. Although the conflicting claims are not identical, they are not patentably distinct from each other because both applications claim a polymeric medical article impregnated with a treatment solution comprising chlorhexidine free base and a chlorhexidine salt. Also, the methods of preparing the article are both drawn to (i) placing the medical article in a solution of comprising (a) a solvent and (b) a mixture of chlorhexidine free base and chlorhexidine salt in a 1:1 ratio and 1:5 weight/weight ratio, (ii) soaking the medial article for an effective amount of time, (iii) removing the article from the solution and (iv) drying the medical article.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

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*Specification*

*Claim Rejections - 35 USC § 103*

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claims 1-3, 8-13, 17-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Solomon et al. (US 621271).

Solomon discloses an anti-infective medical article has chlorhexidine bulk distributed throughout a polyurethane base layer and may have a coating layer on the base layer. The coating layer may be chlorhexidine permeated into the surface or it may be an antibiotic, antithrombogenic agent or a polymeric surface layer laminated into the base layer (see abstract). Preferred articles are polymeric, most preferably a hydrophilic polymeric vascular assess catheter (see col. 4 line 6-7). The chlorhexidine may be melted or may be a solid uniformly distributed in the polymer melt. The melt to be extruded by contain about 0.05% to 10%, preferably about 1 to 5% by weight of chlorhexidine, and may be prepared in any suitable way (see col. 4 lines 56-61). The article having bulk distributed chlorhexidine may be steeped in a solvent solution of chlorhexidine to permeate a layer of chlorhexidine into the surface of the article. An effective coating of chlorhexidine may be obtained when the steeping solution contains from about 1-25%, preferably 5-15% of chlorhexidine. Accordingly, the choice of solvent depends on the form of chlorhexidine being coated and on the temperature contemplated for the steeping solution. Suitable solvents to serve as the steeping medium for chlorhexidine base are water, methylene

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chloride and preferably methanol. For chlorhexidine salts, such as the hydrochloride, acetate, or preferably the gluconate, suitable solvents are methanol, ethanol, and preferably water. Steeping may be carried out for about 2 minutes to 2 hours at a temperature of about 15 to 60 deg. C. It is, of course, evident that a chlorhexidine coating may be formed on either of both the outside and lumen walls of the catheter merely by contacting the desired walls with the steeping solution. Thus, steeping solution may be drawn into the lumen for contact with the lumen wall only, or the lumen may be filled with a solid rod so that the steeping solution contacts only the outside wall (see cols 5-6). Solomon does not disclose the weight/weight ratio of chlorhexidine free base and water-soluble chlorhexidine salt in the solution is between 1:1 to 1:5.

Absent unexpected results, it is the position of the examiner it would have been obvious to one of ordinary skill in the art at the time the invention was made to have determined a suitable % weight of the chlorhexidine free base and water-soluble chlorhexidine salt. Differences in concentration will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration is critical.

5. Claims 1-13, 17-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Solomon et al. (US 621271) in further view of the Merck Index.

Solomon, as disclosed above, teaches an anti-infective medical article has chlorhexidine bulk distributed throughout a polyurethane base layer and may have a coating layer on the base layer. Solomon does not disclose the solvent to be tetrahydrofuran.

The Merck Index discloses tetrahydrofuran as a solvent for high polymers. Furthermore, tetrahydrofuran is miscible with water, alcohols, ketones, esters, ethers and hydrocarbons.

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Absent unexpected results, it would have been obvious to one of ordinary skill in the art the time the invention was made to have modified the composition of Solomon by adding tetrahydrofuran taught by the Merck Index with the solvents taught by Solomon, because tetrahydrofuran a known solvent used for polymers and is miscible with water and alcohols as taught by the Merck Index.

***Response to Arguments***

6. Applicant's arguments filed 7/6/03 have been fully considered but they are not persuasive.

Applicants argue the "271 patent does not disclose, teach or suggest an antimicrobial medical article prepared by treating a polymeric medical article with a solution consisting essentially of one of more solvents and a mixture of chlorhexidine free base and water-soluble chlorhexidine salt, wherein the weight/weight ratio of chlorhexidine free base and water soluble chlorhexidine in solution is between 1:1 to 1:5. The examiner refers to '271 wherein Solomon teaches the article having bulk distributed chlorhexidine may be steeped in a solvent solution of chlorhexidine to permeate a layer of chlorhexidine into the surface of the article. An effective coating of chlorhexidine may be obtained when the steeping solution contains from about 1-25%, preferably 5-15% of chlorhexidine. Accordingly, the choice of solvent depends on the form of chlorhexidine being coated and on the temperature contemplated for the steeping solution. Furthermore, Absent unexpected results, it is the position of the examiner it would have been obvious to one of ordinary skill in the art at the time the invention was made to have determined a suitable % weight of the chlorhexidine free base and water-soluble chlorhexidine salt. Differences in concentration will not support the patentability of subject matter encompassed by

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the prior art unless there is evidence indicating such concentration is critical. Therefore the rejections under 103 (a) have been maintained.

### ***Conclusion***

7. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

### ***Correspondence***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Rachel M. Bennett whose telephone number is (703) 308-8779. The examiner can normally be reached on Monday through Friday, 8:00 A.M. to 4:30 P.M..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page can be reached on (703) 308-2927. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-3592 for regular communications and (703) 308-7924 for After Final communications.


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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1234.

R. Bennett  
September 15, 2003

  
**THURMAN K. PAGE**  
**SUPERVISORY PATENT EXAMINER**  
**TECHNOLOGY CENTER 1600**